## **Complete Summary**

#### **GUIDELINE TITLE**

Treatment of non-small cell lung cancer stage I and stage II: ACCP evidence-based clinical practice guidelines. (2nd Edition)

## **BIBLIOGRAPHIC SOURCE(S)**

Scott WJ, Howington J, Feigenberg S, Movsas B, Pisters K, American College of Chest Physicians. Treatment of non-small cell lung cancer stage I and stage II: ACCP evidence-based clinical practice guidelines (2nd edition). Chest 2007 Sep;132(3 Suppl):234S-42S. [37 references] PubMed

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates previous versions:

- Smythe WR. Treatment of stage I non-small cell lung carcinoma. Chest 2003 Jan;123(1 Suppl):181S-7S.
- Scott WJ, Howington J, Movsas B. Treatment of stage II non-small cell lung cancer. Chest 2003 Jan;123(1 Suppl):188S-201S.

## **COMPLETE SUMMARY CONTENT**

**SCOPE** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

#### **SCOPE**

## **DISEASE/CONDITION(S)**

Non-small cell lung cancer stage I and stage II

#### **GUIDELINE CATEGORY**

Treatment

#### **CLINICAL SPECIALTY**

Family Practice Oncology Pulmonary Medicine Radiation Oncology Thoracic Surgery

#### **INTENDED USERS**

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Patients
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers

## **GUIDELINE OBJECTIVE(S)**

To provide clinically relevant, evidence-based guidelines for the treatment of non-small cell lung cancer stage I and stage II

#### **TARGET POPULATION**

Patients with stage I and stage II non-small cell lung carcinoma

#### INTERVENTIONS AND PRACTICES CONSIDERED

#### Treatment

#### Surgical

- 1. Surgical resection
- 2. Evaluation by board-certified or board-eligible thoracic surgeon
- 3. Conventional surgical resection (lobectomy or greater resection)
- 4. Sublobar (wedge or segmentectomy) resection
- 5. Intraoperative systematic surgical mediastinal lymph node evaluation for accurate pathologic staging
- 6. Video-assisted thoracic surgery (VATS)

## Nonsurgical Therapies

- 1. Percutaneous ablation
- 2. Stereotactic body radiation therapy (SBRT)
- 3. Platinum-based adjuvant chemotherapy
- 4. Curative intent fractionated radiotherapy

#### **MAJOR OUTCOMES CONSIDERED**

#### **METHODOLOGY**

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

#### **Overview**

The American College of Chest Physicians (ACCP) chose the Duke University Center for Clinical Health Policy Research to perform formal systematic reviews of the current evidence in the five new non-small cell lung cancer (NSCLC) topic areas, as well as to provide a search for the existing guidelines, systematic reviews, and meta-analyses in all of the topics areas. In addition, the Agency for Healthcare Quality and Research) AHRQ agreed to fund the BlueCross BlueShield Association Technology Evaluation Center to perform the formal systematic review of literature on small cell lung cancer (SCLC). The Health Outcomes Research Group of the Department of Epidemiology and Biostatistics at Memorial Sloan-Kettering Cancer Center conducted a full-scale review of the literature since the first set of guidelines in the area of screening for lung cancer to assist that particular writing group.

The formal systematic reviews of the five new topic areas were guided by the appropriate chapter editors and their writing committees, in concert with the Executive Committee of the panel.

The two EPC research teams conducted a variety of systematic computerized bibliographic database searches including the following: (1) a search for systematic reviews, guidelines, and meta-analyses published since the last ACCP lung cancer guideline (MEDLINE, The Cochrane Library, National Guidelines Clearinghouse); (2) targeted searches for reviews in each of five selected treatment sections (solitary pulmonary nodules, stage I and II, stage IIIA, stage IIIB, stage IV); these searches, run in OVID version of MEDLINE, were performed in July and August 2005 and were limited to publication years since 1995, English language, and human subjects; and (3) searches related to SCLC are described in the evidence chapter on SCLC.

Search terms included the medical subject heading terms lung neoplasms (exploded) and bronchial neoplasms for the lung cancer concept. Each topic search utilized key words specific to the key questions of interest (complete search strategies are available on request from the authors).

# Strategy Specific for the Treatment of Non-small Cell Lung Cancer Stage I and Stage II

The Duke Evidence-based Clinical Practice Center searched the literature for studies regarding the issues of lymph node staging vs. dissection, surgical

treatment of early stage lung cancer, the use of adjuvant chemotherapy in the treatment of early stage lung cancer, and the use of radiation therapy for primary treatment of early stage lung cancer as well as in the adjuvant setting. The Duke Evidence-based Practice Center found insufficient data were available regarding ablative therapies such as radiofrequency ablation, cryotherapy, and ablation of tumors using microwave emitting probes, and these areas were not included in this evidence-based review. They then provided evidence tables, summaries of studies, and references to other recently published guidelines authored by other organizations for the panel members to review.

## **NUMBER OF SOURCE DOCUMENTS**

Not stated

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

**High** Randomized controlled trials (RCTs) without important limitations or overwhelming evidence from observational studies\*

**Moderate** RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies\*

#### **Low or very low** Observational studies or case series

\*Although the determination of magnitude of the effect based on observational studies is often a matter of judgment, the guideline developers offer the following suggested rule to assist this decision: a large effect would be a relative risk >2 (risk ratio < 0.5) [which would justify moving from weak to moderate], and a very large effect is a relative risk > 5 (risk ratio < 0.2) [which would justify moving from weak to strong]. There is some theoretical justification in the statistical literature for these thresholds (the magnitude of effect that is unlikely or very unlikely to be due to residual confounding after adjusted analysis). However, once the decision is made, authors should be explicit in justifying their decisions.

#### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Quality of evidence is scored in three categories with high-quality evidence obtained from randomized controlled trials (RCTs) without important methodologic limitations based on the study design, the consistency of the results, and the directness of the evidence. In extraordinary circumstances, significant and consistent evidence from observational studies could also be ranked as high

quality. RCTs with important methodologic limitations or flaws, inconsistent results, or indirect or imprecise results would be scored as medium quality, as well as exceptionally strong evidence from observational studies. Other observational studies or case-series data would fall into the low quality of evidence category. It is the interface of the quality of the evidence and the balance of benefits to harms or burdens that determines the strength of the recommendation, with a 1A recommendation being the strongest and 2C the weakest.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Informal Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Writing committees studied the evidence and summary tables or reviewed the literature for their assigned topics, developing their arguments for the recommendations and suggested grading of those recommendations that were put forth for early drafts. The Executive Committee of the panel, composed of the Chair, Vice-Chair, methodologist, and both project managers, reviewed drafts of each chapter of the manuscript during the writing process. Sections that were determined to be potentially overlapping were shared among the appropriate chapter editors, and conference calls were organized to coordinate the placement of these sections and to confirm that there would be no conflicting information or recommendations.

A conference of the panel was convened in July 2006, prior to which time all panelists, including representatives from the invited organizations, were requested to review the complete manuscript and identify recommendations for which the proposal, wording, or grading were determined to be controversial or could be interpreted as controversial by others, incorrectly evolved from the evidence, disagreement existed with regard to the proposal or the grading, or required full panel discussion and further review for any reason. When the panelists who were present were not in unanimous agreement with the proposed recommendations or the grading of the recommendations, informal group consensus techniques were employed. After the meeting, a series of conference calls were convened to finish the discussions and finalize the recommendations. There were a few chapters for which there was insufficient time for full dialogue during the meeting; in the interest of ensuring that the recommendations followed the evidence, the conference calls were necessary. This process ensured the "buyin" of the panelists and was deemed to be a worthwhile effort.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

#### **Grade of Recommendations Scale**

Grade	Recommendation	
1A	Strong	

Grade	Recommendation	
1B	Strong	
1C	Strong	
2A	Weak	
2B	Weak	
2C	Weak	

## Relationship of Strength of the Supporting Evidence to the Balance of Benefits to Risks and Burdens

Balance of Benefits to Risks and Burdens					
Quality of Evidence	Benefits Outweigh Risks/Burdens	Risks/Burdens Outweigh Benefits	Evenly Balanced	Uncertain	
High	1A	1A	2A		
Moderate	1B	1B	2B		
Low or very low	1C	1C	2C	2C	

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

Peer Review

#### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Following final chapter revisions and incorporation of these ultimate recommendations and grading, a concluding review was conducted by the guideline panel Executive Committee. The guidelines were then submitted for review and approval to the American College of Chest Physicians Health and Science Policy Committee (ACCP HSP) Committee, as well as the Thoracic Oncology Network of the college.

#### **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

Definitions for the strength of evidence and recommendation grades (1A-2C) follow the recommendations.

1. For patients with clinical stage I and II non-small cell lung cancer (NSCLC) and no medical contraindication to operative intervention, surgical resection is recommended. **Grade of recommendation**, **1A** 

- 2. For patients with clinical stage I and II NSCLC, it is recommended that they be evaluated by a thoracic surgical oncologist with a prominent part of his/her practice focused on lung cancer, even if they are being considered for nonsurgical therapies such as percutaneous ablation or stereotactic body radiation therapy (SBRT). **Grade of recommendation, 1B**
- In patients with stage I and II NSCLC who are medically fit for conventional surgical resection, lobectomy or greater resection are recommended rather than sublobar resections (wedge or segmentectomy). Grade of recommendation, 1A
- 4. In patients with stage I NSCLC who may tolerate operative intervention but not a lobar or greater lung resection due to comorbid disease or decreased pulmonary function, sublobar resection is recommended over nonsurgical interventions. **Grade of recommendation, 1B**
- 5. In patients with stage I NSCLC who are considered appropriate candidates for thoracoscopic anatomic lung resection (lobectomy or segmentectomy), the use of video-assisted thoracic surgery (VATS) by surgeons experienced in these techniques is an acceptable alternative to open thoracotomy. Grade of recommendation, 1B
- In patients undergoing resection for stage I and II NSCLC, it is recommended that intraoperative systematic mediastinal lymph node sampling or dissection be performed for accurate pathologic staging. Grade of recommendation, 1B
- 7. For patients with centrally or locally advanced NSCLC in whom a complete resection can be achieved with either technique, sleeve lobectomy is recommended over pneumonectomy. **Grade of recommendation, 1B**
- 8. For patients with N1 lymph node metastases (stage II NSCLC) in whom a complete resection can be achieved with either technique, sleeve lobectomy is recommended over pneumonectomy. **Grade of recommendation, 1B**
- 9. For patients with completely resected stage IA NSCLC, the use of adjuvant chemotherapy is not recommended for routine use outside the setting of a clinical trial. **Grade of recommendation**, **1A**
- 10. For patients with completely resected stage IB NSCLC, the use of adjuvant chemotherapy is not recommended for routine use. **Grade of recommendation**, **1B**
- 11. For patients with completely resected stage II NSCLC and good performance status, the use of platinum-based adjuvant chemotherapy is recommended.

  Grade of recommendation, 1A
- 12. For patients with stage I or II NSCLC who are not candidates for surgery ("medically inoperable") or who refuse surgery, curative intent fractionated radiotherapy is recommended. **Grade of recommendation**, **1B**
- 13. For patients with completely resected stage IA or IB NSCLC, postoperative radiotherapy is associated with a decreased survival and is not recommended. **Grade of recommendation, 1B**
- 14. For patients with completely resected stage II NSCLC, postoperative radiotherapy decreases local recurrence but a survival benefit has not been clearly shown; therefore, postoperative radiotherapy is not recommended. **Grade of recommendation**, **1B**

## **Definitions**:

## **Quality of Evidence Scale**

**High** - Randomized controlled trials (RCTs) without important limitations or overwhelming evidence from observational studies\*

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## Low or very low - Observational studies or case series

\*Although the determination of magnitude of the effect based on observational studies is often a matter of judgment, the guideline developers offer the following suggested rule to assist this decision: a large effect would be a relative risk > 2 (risk ratio < 0.5) [which would justify moving from weak to moderate], and a very large effect is a relative risk > 5 (risk ratio < 0.2) [which would justify moving from weak to strong]. There is some theoretical justification in the statistical literature for these thresholds (the magnitude of effect that is unlikely or very unlikely to be due to residual confounding after adjusted analysis). However, once the decision is made, authors should be explicit in justifying their decisions.

#### **Grade of Recommendations Scale**

Grade	Recommendation	
1A	Strong	
1B	Strong	
1C	Strong	
2A	Weak	
2B	Weak	
2C	Weak	

## Relationship of Strength of the Supporting Evidence to the Balance of Benefits to Risks and Burdens

Balance of Benefits to Risks and Burdens					
Quality of Evidence	Benefits Outweigh Risks/Burdens	Risks/Burdens Outweigh Benefits	Evenly Balanced	Uncertain	
High	1A	1A	2A		
Moderate	1B	1B	2B		
Low or very low	1C	1C	2C	2C	

#### **CLINICAL ALGORITHM(S)**

None provided

#### **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

Appropriate treatment for patients with non-small cell lung cancer stage I and stage II

#### **POTENTIAL HARMS**

Not stated

#### IMPLEMENTATION OF THE GUIDELINE

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

The publication of the *Diagnosis* and *Management of Lung Cancer: ACCP Evidence-Based Clinical Practice Guidelines; Second Edition* in *CHEST* is the first of two dissemination vehicles. The circulation of the journal is 23,000 subscribers and libraries, including six translations and distribution to 107 countries. All subscribers received a copy of this full-text guideline. The American College of Chest Physicians (ACCP) Clinical Resource on Lung Cancer is composed of a printed publication and an accompanying CD-ROM, containing a quick reference guide for physicians and other health-care providers, patient-targeted educational materials, and a set of slides for use in educational or clinical contexts. In addition, the recommendations and grading are personal digital assistant downloadable from the clinical resource. This product is available for purchase from the ACCP. The patient education materials are accessible free of charge on www.chestnet.org.

The implementation and translation of evidence-based clinical practice guidelines facilitates knowledge uptake, critical for practice change, and should ultimately lead to better patient-focused care. The HSP Subcommittee on Implementation has proposed to collaborate with the Governors, Thoracic Oncology Network, and other groups within the ACCP to disseminate and implement the guidelines in their local communities. Residency and specialty training programs are encouraged to use the guidelines in journal clubs and grand rounds. Other organizations that were invited to send representatives to the final conference and review the proposed drafts were also requested to endorse the guidelines and market them to their membership through their own communication channels.

#### **IMPLEMENTATION TOOLS**

Patient Resources Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

Getting Better Living with Illness

#### **IOM DOMAIN**

Effectiveness Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

Scott WJ, Howington J, Feigenberg S, Movsas B, Pisters K, American College of Chest Physicians. Treatment of non-small cell lung cancer stage I and stage II: ACCP evidence-based clinical practice guidelines (2nd edition). Chest 2007 Sep;132(3 Suppl):234S-42S. [37 references] PubMed

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### **DATE RELEASED**

2003 Jan (revised 2007 Sep)

## **GUIDELINE DEVELOPER(S)**

American College of Chest Physicians - Medical Specialty Society

## **SOURCE(S) OF FUNDING**

American College of Chest Physicians

#### **GUIDELINE COMMITTEE**

American College of Chest Physicians (ACCP) Expert Panel on Lung Cancer Guidelines

#### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Primary Authors*: Walter J. Scott, MD, FCCP; John Howington, MD, FCCP; Steven Feigenberg, MD; Benjamin Movsas, MD; Katherine Pisters, MD

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Funding for both the evidence review and guideline development was supported by educational grants from AstraZeneca LP, Bristol-Myers Squibb Company, Eli Lilly and Company, Genentech, and Sanofi-Aventis. Representatives from these companies were neither granted the right of review, nor were they allowed participation in any portion of the guideline development process. This precluded participation in either conference calls or conferences. No panel members or ACCP reviewers were paid any honoraria for their participation in the development and review of these guidelines.

The ACCP approach to the issue of potential or perceived conflicts of interest established clear firewalls to ensure that the guideline development process was not influenced by industry sources. This policy is published on the ACCP Web site at <a href="www.chestnet.org">www.chestnet.org</a>. All conflicts of interest within the preceding 5 years were required to be disclosed by all panelists, including those who did not have writing responsibilities, at all face-to-face meetings, the final conference, and prior to submission for publication. The most recent of these conflict of interests are documented in this guideline Supplement. Furthermore, the panel was instructed in this matter, verbally and in writing, prior to the deliberations of the final conference. Any disclosed memberships on speaker's bureaus, consultant fees, grants and other research monies, and any fiduciary responsibilities to industry were provided to the full panel in writing at the beginning of the conference and at submission for publication.

## ENDORSER(S)

American Association for Bronchology - Disease Specific Society
American Association for Thoracic Surgery - Medical Specialty Society
American College of Surgeons - Medical Specialty Society
American Society for Therapeutic Radiology and Oncology
Asian Pacific Society of Respirology - Disease Specific Society
Oncology Nursing Society - Professional Association
Society of Thoracic Surgeons - Medical Specialty Society
World Association of Bronchology - Disease Specific Society

#### **GUIDELINE STATUS**

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This guideline updates previous versions:

- Smythe WR. Treatment of stage I non-small cell lung carcinoma. Chest 2003 Jan;123(1 Suppl):181S-7S.
- Scott WJ, Howington J, Movsas B. Treatment of stage II non-small cell lung cancer. Chest 2003 Jan;123(1 Suppl):188S-201S.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available to subscribers of <u>Chest - The Cardiopulmonary and</u> Critical Care Journal.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

## Executive Summary:

 Alberts MW. Diagnosis and management of lung cancer executive summary. Chest 2007 Sep;132(3 Suppl):1S-19.

## Background Articles:

- Alberts WM. Introduction: diagnosis and management of lung cancer. Chest 2007 Sep;132(3 Suppl):20S-22.
- McCrory DC, Lewis SZ, Heitzer J, Colice GL, Alberts WM. Methodology for lung cancer evidence review and guideline development. Chest 2007 Sep;132(3 Suppl):23S-28.
- Alberg AJ, Ford JG, Samet JM. Epidemiology of lung cancer. Chest 2007 Sep;132(3 Suppl):29S-55.

Electronic copies: Available to subscribers of <u>Chest - The Cardiopulmonary and</u> Critical Care Journal.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

The following is also available:

 ACCP clinical resources: Diagnosis and management of lung cancer: ACCP evidence-based clinical practice guidelines (2nd edition).

Available from the American College of Chest Physicians Web site.

#### **PATIENT RESOURCES**

The following are available:

- Lung cancer guides: lung cancer...am I at risk? Patient education guide. Northbrook (IL): American College of Chest Physicians, 2004. 12 p.
- Lung cancer guides: What if I have a spot on my lung? Do I have cancer?
   Patient education guide. Northbrook (IL): American College of Chest
   Physicians, 2004. 16 p.
- Lung cancer guides: living with lung cancer. Patient education guide. Northbrook (IL): American College of Chest Physicians, 2004. 12 p.
- Lung cancer guides: advanced lung cancer: issues to consider. Patient education guide. Northbrook (IL): American College of Chest Physicians, 2004. 12 p.

Electronic copies: Available in Portable Document Format (PDF) from the American College of Chest Physicians (ACCP) Web site.

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#### **NGC STATUS**

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Date Modified: 9/22/2008

